Enterome announces sustained positive clinical outcomes with EO2401, its lead OncoMimics™ immunotherapy, in combination therapy in Glioblastoma at ASCO

Updated clinical data highlight promising efficacy and sustained CD8+ T cell expansion

Early data from final cohort could provide validation of the EO2401 + nivolumab + bevacizumab combination outcome

Paves the way to next potentially pivotal stage in the clinical development of EO2401 for recurrent Glioblastoma in combination with an immune checkpoint inhibitor and an anti-VEGF therapy

Paris, France – May 31, 2023

Enterome, a clinical-stage company developing first-in-class immunomodulatory drugs for cancer and inflammatory diseases based on its unique Mimicry platform, today announces the presentation of new clinical data from its Phase 2 trial (ROSALIE) evaluating its lead OncoMimics™ immunotherapy candidate EO2401 in combination with an immune checkpoint inhibitor (nivolumab) +/- an anti-VEGF therapy with anti-edema properties (bevacizumab), in patients with first progression/recurrence of glioblastoma (GBM), at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting. ASCO will take place June 2-6, 2023 in Chicago, Illinois.

Nivolumab is used as an adjuvant to EO2401, to support T cell expansion and tumor infiltration. By itself, nivolumab has no observed clinical effect on GBM tumors. Bevacizumab was added to the treatment regimen to counteract immunosuppression by VEGF and to treat neurological symptoms and edema thought to be a result of tumor infiltration by immune cells.

Pierre Belichard, CEO at Enterome said, *"We are thrilled with the clinical and immunological data emerging from the ROSALIE trial, which we are presenting at ASCO. We are seeing elevated and durable increases in CD8+ T cell levels and a strong correlation to improved clinical outcomes for certain patients, particularly those receiving the triple combination of EO2401, nivolumab and bevacizumab. These findings, along with the broader insights gained from ROSALIE, pave the way to the next potentially pivotal stage in the clinical development of EO2401 in glioblastoma and for the advancement of our unique OncoMimics™ immunotherapy portfolio in solid and liquid tumors."*

Key highlights from the Phase 2 ROSALIE trial poster presentation are:

- Data published to date confirm that EO2401 in combination with nivolumab +/- bevacizumab is well tolerated with a safety profile consistent with the safety profiles of nivolumab and bevacizumab alone, with the addition of local administration site reactions.

- Immune monitoring in peripheral blood demonstrated the ability of EO2401 to expand OncoMimic™-specific CD8+ T cells with cross-reactivity against the targeted human tumor-associated antigens (TAAs) in a significant portion of patients. Memory specific CD8+ T cell responses were found as early as two weeks after the first vaccination and maintenance of a strong and stable immune response could be detected for up to 23 months.

- EO2401 in combination with nivolumab generated strong systemic immune responses through activation of specific CD8+ T cells, correlating with clinical efficacy.

- EO2401/nivolumab without efficacious anti-edema treatment shows the same efficacy as current standard of care with survival around nine months. Edema in some patients resulted in neurological symptoms leading to short treatment durations.

- The addition of symptom-directed low-dose bevacizumab as an anti-edema treatment to EO2401/nivolumab prolonged treatment duration and improved all efficacy parameters (survival around 12.5 months).

- EO2401/nivolumab with continuous standard bevacizumab added from the start further improved median treatment duration and efficacy (survival around 14.5 months).

- Early data from final cohort (N=15) presented for the first time at ASCO gives hope regarding validation of the EO2401/nivolumab/bevacizumab triple combination regimen and outcome.

- Patient enrollment was completed in late 2022. Further data will be presented in 2023.

Details on Enterome's ROSALIE study (EOGBM1-18) poster presentation at ASCO are as follows:

- **Title:** *EO2401 (E) peptide immunotherapy + nivolumab (N) +/- bevacizumab (B) in recurrent glioblastoma (GB); EOGBM1-18/ROSALIE*
- **Presenter:** Wolfgang Wick, MD, Universitätsklinikum Heidelberg and German Cancer Research Center, Heidelberg, Germany
- **Track:** Central Nervous System Tumors (Poster Board 377)
- **Abstract Number:** 2020
- **Date and Time:** Saturday, June 3, 1:15 - 4:15 PM CDT; Discussion 4.30 - 6:00 PM CDT

The abstract #2020 is available here.

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About EO2401

EO2401 is Enterome's first-in-class off-the-shelf OncoMimics™ peptide-based immunotherapy. It combines three microbial-derived OncoMimics™ peptides that closely mimic specific cytotoxic T cell (CD8+ T cell) epitopes on the Tumor-Associated Antigens IL13Ra2, BIRC5 and FOXM1, combined with the helper peptide (CD4+ T cell epitope) Universal Cancer Peptide 2 (UCP2). EO2041 is designed to trigger the immune system into recognizing these epitopes on

glioblastoma cells as foreign (non-self) and eliciting a targeted memory T-cell driven cell-killing response against the tumor cells.

EO2401 is also being evaluated in a Phase 2 clinical trial in combination with nivolumab +/- bevacizumab, for the treatment of adrenal tumors (SPENCER study, EOADR1-19).

About ROSALIE

ROSALIE (EOGBM1-18, NCT04116658) is a multicenter, open-label, Phase 1/2 trial investigating EO2401 in combination with nivolumab +/- bevacizumab in patients with glioblastoma at first progression/recurrence after surgery and adjuvant radiotherapy/temozolomide. The trial is assessing safety, tolerability, immunogenicity and preliminary efficacy in 100 patients at centers in the US and Europe. Patient enrollment was completed in late 2022.

Contacts

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About Enterome

Enterome is a clinical-stage biopharmaceutical company developing breakthrough immunomodulatory drugs for the treatment of cancer and immune diseases. Enterome's pioneering approach to drug discovery is based on its unique and powerful bacterial Mimicry drug discovery platform, allowing it to analyze and uncover new biological insights from the millions of gut bacterial proteins in constant cross-talk with the human body. Its first-in-class small protein and peptide drug candidates modulate the immune system by closely mimicking the structure, effect or actions of specific antigens, hormones, or cytokines.

The company's two pipelines of drug candidates include:

- **OncoMimics™** peptides, a pipeline of peptide-based immunotherapies. Lead candidate, EO2401, is in Phase 2 clinical trials in patients with glioblastoma and adrenal tumors and has demonstrated clinical proof of concept. EO2463 is in a Phase 1/2 clinical trial for indolent non-Hodgkin lymphomas, with clinical data expected in H1 2023. EO2040, a new immune therapy, is expected to start a Phase 2 trial in 2023 in patients suffering from colorectal cancer with ctDNA-defined, minimal residual disease. EO4010 is in development for third-line colorectal cancer and targeted to enter clinical trials in 2023.
- **EndoMimics™** peptides, a pipeline of next generation bioactives acting like human hormones or cytokines, are being developed in collaboration with Nestlé Health Science, for food allergies and inflammatory bowel disease (IBD). Lead candidate, EB1010, expected to enter the clinic in 2024, is a potent local inducer of IL-10, designed to improve therapeutic outcomes for patients with IBD.

Enterome employs 70 people and is headquartered in Paris, France. Since its inception, the company has raised a total of €116 million from Europe- and US-based life science investors and more than €100 million from pharmaceutical partnerships.

For more information, please visit the company's website at: **www.enterome.com**